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Essential Derivation and Dependence - Practical Information

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Essential Derivation and Dependence

Practical Information

WHY THE CONCEPT OF ESSENTIAL DERIVATION?

The 1978 Act of the UPOV Convention (International Union for the Protection of New Varieties of Plants) states that "the authorization by the breeder shall not be required either for the utilization of the [his protected] variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties".

That principle, known as the "breeder's exemption", is essential for continued progress from plant breeding.

However, its implementation has progressively led to some abuses, due to the difficulties involved with assessment of distinctness, based on the text of the Convention (1978) which indicates that, for the basis of a title of protection, "the [new] variety must be clearly distinguishable by one or more important characteristics from any other variety whose existence is a matter of common knowledge ...".

Sometimes, "cosmetic modifications" were enough for protecting a new variety. That was particularly true in the case of mutation of ornamental or fruit plants and of "conversion" by repeated backcrossing of parental lines of hybrid varieties.

In order to improve the situation, in the early 1980's, a debate began on how to improve the system, trying to define "minimum distances" per species, but no consensus was reached. The development of genetic engineering, opened new possibilities for "piracy" of varieties and sped up the revision process of the Convention which in the Act adopted in 1991, has introduced with the full agreement of breeders' associations, the concept of essential derivation. That concept of essential derivation has two aspects:

- a technical one: the question whether or not a plant variety is to be considered as a variety essentially derived from an initial variety;
- a juridical one: dependence, meaning that no protected acts as defined by the 1991 Act of the UPOV Convention (production, marketing ...) related to the essentially derived variety shall be carried out without the authorization of the owner of the protected initial variety.

DEFINITION OF AN ESSENTIALLY DERIVED VARIETY

The 1991 Act of the UPOV Convention states that "a variety shall be deemed to be essentially derived from another variety (the initial variety) when:

1. It is **predominantly derived** from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial

APPENDIX 2

http://www.worldseed.org/Position_papers/derive.htm

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variety:

- ii. it is clearly distinguishable from the initial variety and
- iii. except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

Essentially derived varieties may be obtained, for example, by selection of natural or induced mutants, by selection of a somaclonal variant, by selection of variant individual plants in the initial variety, by backcrossing or by transformation (genetic engineering).

ASSINSEL interprets the definition given in the Convention as follows:

a) The technical aspects (matter of facts)

For a variety to be considered as essentially derived, it must fulfil three requirements in relation to the initial variety while retaining the expression of the essential characteristics of the initial variety:

- i. clear distinctness in the sense of the UPOV Convention
- ii. conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety
- iii. predominant derivation from an initial variety.

If one of these requirements is not fulfilled, there is no essential derivation.

The methods of breeding that can be regarded as leading to an essentially derived variety (see the above-mentioned explanatory list) may differ from species to species or even within a species. This may result in different thresholds being required to characterize essential derivation. Thus, conformity should be judged on a species-by-species or even within a species basis.

b) The juridical aspect

The principle of dependence only exists in favour of a protected variety. This means that:

- i. the initial variety must be a protected one
- ii. dependence can only exist from one protected variety alone
- iii. an essentially derived variety can be directly derived from the initial variety or from a variety that is itself predominantly derived from the initial variety. It is possible to have a "cascade" of derivation. However, each essentially derived variety shall only be dependent on one, the protected initial variety. A cascade of dependence shall not exist, the principle having been introduced to better protect the breeder of the initial variety and not those having made derivations from his work.

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ASSESSMENT OF ESSENTIAL DERIVATION

The assessment of essential derivation needs to take into account the three criteria mentioned above:

- clear distinctness in the sense of the UPOV Convention
- conformity to the initial variety in the expression of the essential characteristics that result from the genotype or the combination of genotypes of the initial variety
- predominant derivation from an initial variety.

The first criterion will be decided upon by the office in charge of granting a right to the breeder of the variety, according to the UPOV rule of distinctness.

The second criterion could be based on reliable phenotypic characteristics and/or on reliable molecular characteristics: either close relationship in general which could lead to a "conformity threshold" parallel to the minimum distance threshold used for distinctness or only small differences in some simply inherited characteristics. If this second criterion is considered as fulfilled, then, we have to assess the third one, which is "predominant derivation from an initial variety".

The third criterion, predominant derivation from an initial variety, implies that the initial variety or products essentially derived therefrom have been used in the breeding process.

In order to prove that use, various criteria or a combination thereof may be used:

- combining ability
- phenotypic characteristics
- molecular characteristics.

These criteria will have to be handled differently from their use for assessment of distinctness. Whatever solution retained, one will probably have to use distance coefficients to define thresholds. Up to now, ASSINSEL has essentially worked on thresholds based on distances measured by molecular markers. Geneticists and statisticians consider that technically it is equally possible to measure distance coefficients using phenotypic markers. However, the process would probably be more difficult due to environmental factors, and much more expensive: necessity of several testing locations during several years. However, if breeders prefer to use morphological markers instead of molecular markers, that should be possible.

The interest of using combining ability and the heterosis level will strongly depend on the crop. Thresholds will also be necessary.

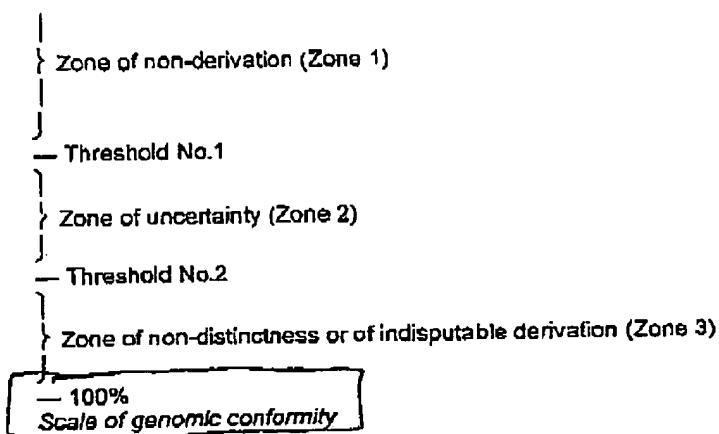
The various ASSINSEL Sections are considering the establishment of thresholds for characterization of essential derivation according to this following general principle:

- One should propose, species by species, a first threshold below which a variety should be considered as non-essentially derived from an initial variety and a second threshold of conformity above which the new variety should be considered as essentially derived, except if the breeder can prove, by clear evidence, that he has started from independent germplasm.
- Between those two thresholds, the derivation could be disputable and the breeder of the putative essentially derived variety should have to give, in case of amicable negotiation or arbitration, information on the origin of the new variety. Should that information be unsatisfactory, the tribunal or of arbitrators/conciliators agreed on by both parties may request breeding records be provided for their examination.

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This approach may be diagrammed as follows:



Some breeders are developing such scheme and call the zone No.1 "green zone", in which breeders would have freedom to operate. Zone No.3, the "red zone", where the breeder would know, according to his breeding materials, if his new variety is obviously essentially derived and dependent. Zone No.2 is where there would be uncertainty and where discussion may be appropriate. The threshold levels would be established first as an experiment. They could be further modified according to the experience acquired in the implementation of the scheme.

While this approach may be worthwhile, it also presents some obvious difficulties:

- ➡ Breeders have so far been unable to agree on threshold levels for any species;
- ➡ Even if the thresholds adopted by the industry had merit, they will not represent an absolute certainty and a court of law could pass judgment on other bases or guidelines.

Nevertheless, this approach does provide some framework in which breeders might proceed.

CONSEQUENCES FOR THE BREEDERS

The concepts of derivation and dependence do not, fortunately, abolish the "breeder's exemption" which is still stated in the 1991 Act. However, "cosmetic" improvement or plagiarism, which could sometimes have allowed the creation of distinct varieties in the sense of the UPOV Convention, will no longer allow the creation of independent varieties. The consequences for the breeders, the farmers and biological diversity more broadly should be positive and will certainly impact the breeder's work.

a) Choice of the parents

Breeders should be certain of their legal access and freedom to use all parent materials employed in their breeding programs. They would have to pay more attention to the results of their breeding work when working with protected varieties within the "breeder's exemption".

b) Breeding methods

Any conventional breeding method could, in theory, provide an essentially derived

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variety. Certain methods appear to give a higher risk of developing essentially derived varieties. Among these methods we include:

- ⊕ natural or induced mutations;
- ⊕ repeated backcrosses: (discussions still continue on the number of backcrosses which could lead to an essentially derived variety. As shown in the French text of the 1991 Convention, which is of evidence, the authors of the Convention had in mind at least two backcrosses, the word being written in plural. However, it must be noted that the selection pressure exerted after the backcross(es) can have an important effect on the final result).
- ⊕ selection in an existing variety, for example the choice of clones in a synthetic variety;
- ⊕ transformation by genetic engineering.

c) Development of technical information

Conformity thresholds for essential derivation, such as presented above, can be defined in the frame of professional agreement (which would be the solution) or, in a case-by-case basis, in decisions by courts of law. In either case, thresholds will come to exist in the years ahead. To know their freedom to operate in relation to such thresholds, breeders will need:

- ⊕ a good knowledge of the range of phenotypic, molecular and physiological variability of varieties present in the market;
- ⊕ to know the phenotypic, molecular and physiological profiles of their genetic material and their experimental varieties, as well as their breeding histories and documentation of legal access.

Breeders will need to employ the tools necessary for assessing such profiles in their research programs. Such tools will not only be used for the protection of intellectual property, but should also promote improvement of breeding efficiency.

d) Keeping of breeding books

Conformity thresholds only, at least in the zone of uncertainty (orange:zone), will not allow a decision on derivation and dependence. In case of litigation, information on parental material and breeding methods will be needed. Thus, breeders will need to maintain clear and accurate breeding records. We encourage breeders to seek competent professional legal advice on the best ways to develop and maintain these important records.

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Essentially Derived Variety

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What is an "Essentially Derived Variety"?

The concept of essentially derived variety was introduced into the 1991 Act of the UPOV Convention in order to avoid plagiarism through mutation, multiple back-crossing and to fill the gap between Plant Breeder's Rights and patents, gap which was becoming important due to the development of the use of patented genetic traits in genetic engineering.

An essentially derived variety is a variety which is distinct and predominantly derived from a protected initial variety, while retaining the essential characteristics of that initial variety.

As indicated as an example in the UPOV Convention, essentially derived varieties may be obtained by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, back-crossing, or transformation by genetic engineering.

The commercialization of an essentially derived variety needs the authorization of the owner of the rights vested in the initial variety.

The concept of essentially derived variety does not at all abolish the Breeder's Exemption, as free access to protected plant varieties for breeding purposes is maintained. It is not a threat to biodiversity. On the contrary, it favors biodiversity, encouraging breeders developing and marketing original varieties.

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